



Docket No.: V9661.0074

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent Application of: Hsiang-Fu Kung et al.

Application No.: 10/801,648

Confirmation No.: 2232

Filed: March 17, 2004

Art Unit: 1633

For: COMBINED ADENO-ASSOCIATED VIRUS  
AND ADENOVIRUS COCKTAIL GENE  
DELIVERY SYSTEM FOR HIGH  
EFFICIENCY GENE EXPRESSION  
WITHOUT ELICITING IMMUNE RESPONSE  
IN IMMUNO-COMPETENT SUBJECTS

Examiner: R. M. Kelly

New York, NY  
June 30, 2006

**INFORMATION DISCLOSURE STATEMENT (IDS)**

U.S. Patent and Trademark Office  
220 20th Street S.  
Customer Window  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

**Timing of Filing of the Information Disclosure Statement:**

☐ This IDS is being filed before the First Office Action<sup>1</sup>.

<sup>1</sup> The IDS should, where possible, include a certification under 37 C.F.R. §1.97(e).

- ☒ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action<sup>2</sup>.
- ☐ This IDS is being filed after the issuance of a Final Office Action, Ex Parte Quayle Action or Notice of Allowance but before the payment of the Issue Fee<sup>3</sup>.

**Certifications:**

If checked, the undersigned makes the following statement(s):

- ☐ Statement under 37 CFR § 1.97(e):

Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

- ☐ Statement Under 37 C.F.R. § 1.704(d):

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<sup>2</sup> The IDS *must* include *either* a certification under 37 C.F.R. §1.97(e) *or* the fee set forth in 37 C.F.R. §1.17(p).

<sup>3</sup> The IDS *must* include *both* a certification under 37 C.F.R. §1.97(e) *and* the fee set forth in 37 C.F.R. §1.17(p).

Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application less than thirty days prior to the filing of this information disclosure statement.

**Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):**

☒ If checked, the fee of \$180.00 set forth in 37 C.F.R. §1.17(p) is attached.

**Copies of Information:**

In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

☒ A legible copy<sup>4</sup> of each document (or relevant portion thereof) cited in the attached PTO/SB/08, except for U.S. patent and U.S. published applications.

☐ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, is attached.

This concise explanation is provided by way of:

☐ A translation of the relevant portions of the non-English language information<sup>5</sup>;

☐ A statement explaining the relevant portions of the non-English language information;

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<sup>4</sup> A legible copy of the document is not required if (1) the information was previously cited by, or submitted to, the Office and considered by the Office in a prior U.S. application to which this application claims priority, provided that the prior application is properly identified in this IDS, and (2) the IDS submitted in the earlier application complies with 37 C.F.R. § 1.98(a) – (c). This exception does not apply to information cited in an International Application.

<sup>5</sup> 37 C.F.R. §1.98(a)(3)(ii) *requires* that an English language translation be provided when a translation of the document, or portion thereof, “is within the possession, custody or control of, or is readily available to any individual designated in 37 C.F.R. § 1.56(c).”

☐ A copy [and, where not in the English language, a translation] of at least the relevant portion(s)<sup>6</sup> of the communication from a foreign patent office in a counterpart foreign application in which the information was cited; or

☐ This information is contained in the specification of the present application.

☐ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

**Materiality:**

Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

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<sup>6</sup> The relevant portion is that portion which indicates the degree of relevance found by the foreign patent office. This may be an explanation of which portion of the of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report. MPEP §609 III A(3).


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In the event the actual fee is inadvertently not enclosed or if any additional fee during the prosecution of this application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 50-2215.

Dated: June 30, 2006

Respectfully submitted,

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/801,648-Conf. #2232	
			Filing Date	March 17, 2004	
			First Named Inventor	Hsiang-Fu Kung	
			Art Unit	1633	
			Examiner Name	R. M. Kelly	
Sheet	1	of	1	Attorney Docket Number	V9661.0074

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CG2	Review "Current Status of Gendicine in China: Recombinant Human Ad-p53 Agent for Treatment of Cancers"; Zhaohui Peng, Human Gene Therapy 16:1016-1027 (September 2005)	
	CH2	"Generation of a High-Capacity Hybrid Vector: Packaging of Recombinant Adenoassociated Virus Replicative Intermediates in Adenovirus Capsids Overcomes the Limited Cloning Capacity of Adenoassociated Virus Vectors"; Manuel A. F.V. Goncalves, et al.; Virology 288, 236-246 (2001).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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